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Japan

Biotechnology

Annual Report

2007

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Report Highlights:
Japan is the world's largest importer of foods and feeds that have been produced using modern biotechnology. To date, Japan has approved 77 biotech events for food, 50 for feed, 55 for planting and 14 for food additives. A surge in new biotech applications is expected over the next two years and this will pose challenges to the regulatory system. Japan ratified the Biosafety Protocol in November 2003 and has implemented mandatory biotech labeling on certain foods containing biotech derived ingredients. In general, biotech products for direct consumer use are not yet well received by the Japanese food industry or consumers. Japan does not produce any biotech products commercially but does have several under development. This report contains current information on approved biotech events, updates on Japan's regulatory system, biotech research initiatives, and information related to the sale and marketing of biotech crops.

Includes PSD Changes: No
Includes Trade Matrix: No
Annual Report
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Executive Summary

Japan is a large importer of grains that have been produced using modern biotechnology, including about 12 million metric tons of U.S. feed corn and 4.5 million metric tons of U.S. soybeans annually. Conversely, the Japanese public and food industry are reluctant to accept agricultural biotechnology products. In response, the Japanese government has taken extensive regulatory measures to address public concerns. These include mandatory biotech labeling, mandatory safety food and feed review systems, and domestic regulations that implement a Biosafety Protocol-based environmental review system.

The Ministry of Health, Labor and Welfare (MHLW) is responsible for the food safety of biotech products, while the Ministry of Agriculture, Forestry and Fisheries (MAFF) is in charge of feed and environmental safety. The Food Safety Commission (FSC), an independent risk assessment body established in July 2003, performs food and feed safety risk assessment for MHLW and MAFF. As of June 2007, Japan has approved 91 biotechnology products for food, 77 events and 14 food additives. It is illegal to import biotech-derived products that have not been approved. Japanese regulatory agencies extensively test and use other enforcement tools, even when there is no apparent health or environmental concern.

Japan does not commercially produce plants that have been enhanced using modern biotechnology. A number of public research institutes are carrying out plant biotechnology research but most have not progressed to the field trial stage because of strong consumer concerns. Because there is no market for biotech seeds in Japan, the private sector has little incentive to develop Japan-specific varieties of biotech crops. The major agricultural biotechnology companies maintain offices in Japan but their primary function is to navigate Japan's complex regulatory approval process for imported biotech foods and feed.

On June 1, 2007, the Japanese Cabinet decided on mid and long-term policy goals called 'Innovation 25,' which, among other things, calls for an 'Increase of public awareness on biotechnology, especially agricultural biotechnology.' On July 6, 2007, MAFF announced a Biodiversity Strategy that emphasizes the importance of biodiversity in local ecosystems as well as the sustainable application and preservation of beneficial genetic resource and the importance biotechnology regulation under the Cartagena Protocol. On July 9, 2007, a MAFF-established panel published and interim report identifying seven biotech research priorities, including functional foods (e.g., rice with high GABA accumulation), crops resistant to complex pests (e.g., rice resistant to both filamentous fungi and bacteria) and biofuels.

Japan requires biotech labeling for food products in which traces of biotechnology derived DNA or protein can be found. However, there are currently no labeled consumer-ready products in general commerce. Food manufacturers, without exception, request U.S. suppliers to provide non-biotechnology products that are produced using a documented identity preservation (IP) system. However, many manufacturers of foods that fall outside of the labeling requirement, such as soybean oil, utilize biotech products. Animal feeds also commonly use biotech corn and soybean meal.

In order to label a product as specifically being 'non-biotech,' food manufactures must use an identity preservation (IP) system. Non-biotech labeling is done for marketing reasons and is common.

Production

There is no commercial production of biotech crops in Japan. A few pioneering farmers have in the past "experimentally" grown biotech soybeans in Japan in order to confirm their benefits. The 'experiment' was terminated before the crop flowered due to concerns from surrounding farmers about cross pollination and concerns from agricultural cooperative opposing biotech crops. There are numerous local restrictions on growing biotech crops in Japan (see section III, Local Government Regulations). These not only discourage commercial production but also are a growing barrier to seed companies that carry out mandatory field-testing as part of the regular biotech crop approval process.

Consumption

Japan produces only five percent of its corn. Japan is the largest export market for U.S. corn, valued at $1.9 billion in CY 2006. Of the 16.2 million metric tons (MMT) imported, about 10 million MMT was used for feed. In addition to feed corn, nearly six MMT of U.S. 'GM Free' food use corn is shipped annually to Japan under an identity preservation system. The vast

majority of feed corn is either biotech or "non-segregated" corn. Food use corn is segregated and often commands a significant premium over feed corn. There is little resistance to the use of biotech crops in the production of vegetable oil. For example, oil from biotech soy, canola, cottonseed or corn oil may be sold without a 'GMO' label.

Trade

Japan is one of the largest food importers in the world with around 40% of its food being imported (on a calorie basis). Japan relies heavily on imports of corn and soybeans, two major biotech crops produced in the United States. Japan also imports biotech canola, mainly from Canada.

In order to avoid having to labeling foods as " containing biotech" almost all retailers require that food use corn and soybeans be supplied as IP handled non-biotech products. The U.S. supplies about 95% of Japan's 16 million MT of corn imports per year. Corn for feed accounts for 12 million MT of the total and is generally not segregated or IP handled. The remaining 4 million MT is IP corn for food use.

For soybeans, Japan imports about 4.5 million MT per year, including 3.5 million MT from the United States. Around 3.5 million MT of soybeans are used for crushing annually. Since vegetable oil is exempted from labeling requirements, almost all of the soybeans imported for crushing are not segregated. The soybean food industry (tofu, etc) demands soybean importers supply non-biotech food grade beans to be used as raw ingredients.

Regulatory Framework

In Japan, commercialization of biotech plants products requires environmental, food, and feed approvals. Four ministries are involved in the regulatory framework; the Ministry of Agriculture, Forestry and Fisheries (MAFF), the Ministry of Health, Labor and Welfare (MHLW), Ministry of Environment (MOE), and the Ministry of Education, Culture, Sports, Science and Technology (MEXT).

Risk assessments and safety evaluations are performed by each ministry's advisory committees and scientific expert panels. The assessments and evaluations are performed by the scientific expert panels, which mainly consist of researchers of universities and public research institutions. The decisions by the expert panels are reviewed by the advisory committees whose members include technical experts and opinion leaders from a broad scope of interested parties such as consumers and industry. The advisory committees report back the decision to the responsible ministries. The minister of each ministry then the typically approves the product.

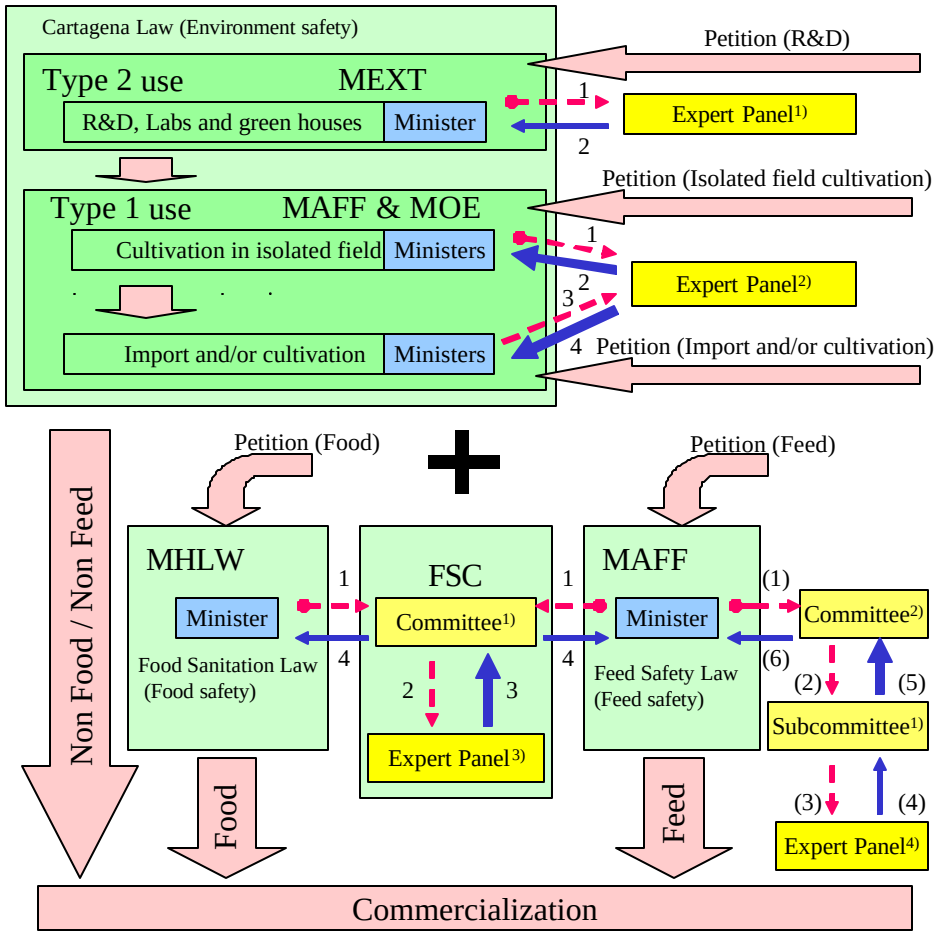
Japan ratified the Biosafety Protocol in November 2003. To implement the Protocol, in February 2004, Japan promulgated the 'Law Concerning the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Living Modified Organisms' also called the "Cartagena Law". Under the law, MEXT requires its minister's approval before performing early stage agricultural biotech experiments in laboratories and greenhouses. MAFF and MOE require their Ministers' joint approvals for the use of biotech plants in an isolated field for the evaluation of influences on biodiversity (Type 2 use). After the necessary scientific data are collected through the isolated field experiments, under permission by MAFF and MOE Ministers, a risk assessment of the event will be done through the use of field trials (Type 1 use). A joint MAFF and MOE expert panel carries out the environmental safety evaluations. Non-food biotech plant products such as flowers may be produced commercially once the Type 1 use risk assessment is completed.

Biotech plants that are used for food must obtain food safety approvals from the MHLW Minister. Based on the Food Sanitation Law, and upon receiving a petition for review from an interested party (usually a biotech company), the MHLW minister will request the Food Safety Commission (FSC) to review the food safety of the biotech products. The FSC is an independent government organization under the Cabinet Office that was established to perform food safety risk assessments by expert committees. Within the FSC there is a 'Genetically Modified Foods Expert Committee,' consisting of plant biotech scientists from universities and public research institutes. The Expert Committee conducts the actual scientific review. Upon completion, the FSC provides its risk assessment conclusions to the MHLW Minister. The standards

used by the FSC for food risk assessment of biotech foods are available in English at the following website: (http://www.fsc.go.jp/senmon/idensi/gm_kijun_english.pdf).

Biotech products that are also used as feed must obtain approvals from the MAFF Minister based on the Feed Safety Law. Upon requests from petitioners, the MAFF Minister asks the Experts Panel on Recombinant DNA Organisms, which is part of the MAFF affiliated Agricultural Materials Committee (AMC), to review the event. The Expert Panel evaluates feed safety on livestock animals, which is then reviewed by the AMC. The MAFF Minister also asks the FSC Genetically Modified Foods Expert Committee to review any possible human health effects from consumption of livestock products from animals fed with biotech event under review. Based on the reviews of AMC and FSC, the MAFF Minister grants approval for the feed safety of biotech plants. Following is a schematic chart of the flow of the approval process.

Biotech products that require new standards or regulations not related to food safety, such as labeling or new risk management procedures including IP handling protocols, may need to be discussed by the Pharmaceutical Affairs and Food Sanitation Council of MHLW, and/or Japan Agricultural Standards Council of MAFF.



Expert Panel1): Expert Panel on Recombinant DNA Technology, Bioethics and Biosafety Commission, Council for Science and Technology, MEXT
Expert Panel2): Experts with special knowledge and experience concerning adverse effect on biological diversity selected by MAFF/MOE Ministers
Expert Panel3): Genetically Modified Foods Expert Committee, FSC
Expert Panel4): Expert Panel on Recombinant DNA Organisms, Agricultural Materials Council, MAFF
Committee1): Food Safety Commission
Committee2): Feed Committee, Agricultural Materials Council, MAFF

Subcommittee[1]): Safety Subcommittee, Feed Committee, Agricultural Materials Council, MAFF

Red (broken) arrow: Request for review or risk assessment
Blue (solid) arrow: Recommendation or risk assessment results (thick arrows: with public comment periods)
Numbers beside the arrows indicate the order of requests/recommendations within the respective ministries.

Petitions for products within the R&D stage are reviewed first for the Type 2 use under the Cartagena Law and those for import and/or cultivation (products in the R&D stage whose safety are already confirmed) are reviewed for the Type 1 use, and food and/or feed, as necessary. Petitions for products imported only as non-LMO such as processed foods are reviewed only for food and/or feed review.

This chart outlines principle flow of the approval procedure in Japan, and the process may vary depending on the nature of individual biotechnology product.

Approved Biotech Products

As of June, 2007,Japan has approved 77 biotech events for food, 50 for feed, 55 for planting and 14 for food additives. Until the Biosafety Protocol was ratified in November 2003, Japan had approved 106 events for import and 74 for planting. Those approvals expired when the new legal framework under the Biosafety Protocol was introduced except for those developers who requested to maintain the approvals temporarily. All products approved prior to the ratification of the Biosafety Protocol must be reviewed before being re-approved. Currently under the Biosafety Protocol, Japan does not grant separate environment approvals for import and planting.

List of the approved events of biotech crop.

Plant	Name of event	Applicant/Developer	Characteristics	Approvals		
				BSP (OECD UI)	Feed	Food
Alfalfa	J101	Monsanto Japan	Herbicide tolerant	2006 (MON-00101-8)	2006	2005
	J163	Monsanto Japan	Herbicide tolerant	2006 (MON-00163-7)	2006	2005
	J101 x J163	Monsanto Japan	Herbicide tolerant	2006 (MON-00101-8 × MON-00163-7)	2006	2005
Canola	RT73	Monsanto Japan	Herbicide tolerant	2006 (MON-00073-7)	2003	2001
	HCN92	Bayer Crop Science	Herbicide tolerant	2007 (Topas19/2, ACS-BN007-1)	2003	2001
	HCN10	Bayer Crop Science	Herbicide tolerant		2003	2001
	PGS1	Bayer Crop Science	Herbicide tolerant	2004* (ACS-BN004-7xACS-BN001-4)	1996	2001
	PHY14				1998	2001
	PHY35				1998	2001
	T45	Bayer Crop Science	Herbicide tolerant	2004* (ACS-BN008-2)	1997	2001
	PGS2	Bayer Crop Science	Herbicide tolerant, male sterile, sterility recovery	2004* (MS1RF2, ACS-BN004-7xACS-BN002-5)	1997	2001
	PHY36				1997	2001
	PHY23				1999	2001
	Oxy-235	Bayer Crop Science	Herbicide tolerant	2004* (ACS-BN001-5)	1999	2001
	MS8RF3	Bayer Crop Science	Herbicide tolerant, male sterile, sterility	2004* (ACS-BN005-8xACS-BN003-6)	1998	2001

			recovery			
	MS8	Bayer Crop Science	Herbicide tolerant, male sterile	2006 (ACS-BN005-8)	2003	2001
	RF3	Bayer Crop Science	Herbicide tolerant, sterility recovery	2007S(ACS-BN003-6)	2003	2001
	RT200	Monsanto Japan	Herbicide tolerant	2006 (MON-89249-2)	2003	2001
Carnation	11	Florigene/Suntory	Color change	2004 (FLO-07442-4)	N/A	N/A
	123.2.38	Florigene/Suntory	Color change	2004 (FLO-40644-4)	N/A	N/A
	123.8.8	Suntory	Color change	2004 (FLO-40685-1)	N/A	N/A
	123.2.2	Suntory	Color change	2004 (FLO-40619-7)	N/A	N/A
	11363	Suntory	Color change	2004 (FLO-11363-1)	N/A	N/A
Corn	T-14	Bayer Crop Science	Herbicide tolerant	2006 (ACS-ZM-002-1)	2005	2001
	T-25	Bayer Crop Science	Herbicide tolerant	2004 (ACS-ZM003-2)	2003	2001
	MON810	Monsanto Japan	Insect resistant	2004 (MON-00810-6)	2003	2001
	Bt11	Syngenta Seeds	Insect resistant	2007 (SYN-BT011-1)	2003	2001
	Sweet corn, Bt11	Syntenta Seeds	Insect resistant, herbicide tolerant		-	2001
	Event176	Syngenta Seeds	Insect resistant	2007 (SYN-EV176-9)	1996	2001
	GA21	Monsanto Japan	Herbicide tolerant	2005 (MON-00021-9)	1999	2001
	DLL25	Monsanto Japan	Herbicide tolerant	2006 (DKB-89790-5)	2000	2001
	DBT418	Monsanto Japan	Insect resistant, herbicide tolerant	2007 (DKB-89614-9)	2000	2001
	NK603	Monsanto Japan	Herbicide tolerant	2004 (MON-00603-6)	2003	2001
	MON863	Monsanto Japan	Insect resistant	2004 (MON-00863-5)	2003	2002
	1507	Dow Chemical	Insect resistant and herbicide tolerant	2005 (DAS-01507-1)	2002	2002
	MON88017	Monsanto Japan	Insect resistant, herbicide tolerant	2006 (MON-88017-3)	2006	2005
	Mon863 x NK603	Monsanto Japan	Herbicide tolerant, Insect resistant	2004 (MON-00863-5xMON-00603-6)	2003	2003
	GA21 x MON810	Monsanto Japan	Herbicide tolerant, Insect	2005 (MON-00021-9xMON-	2001	2003

			resistant	00810-6)		
	NK603 x Mon810	Monsanto Japan	Herbicide tolerant, Insect resistant	2004 (MON-00603-6xMON-00810-6)	2002	2003
	Mon810 x T25	DuPont	Herbicide tolerant, Insect resistant	2005 (ACS-ZM003-2xMON-00810-6)	2001	2003
	1507 x NK603	DuPont	Herbicide tolerant, Insect resistant	2005 (DAS-01507-1xMON-00603-6)	2003	2004
	Mon810 x Mon863	Monsanto Japan	Insect resistant	2004 (MON-00810-6xMON-00863-5)	2004	2004
	Mon863 x MON810 x NK603	Monsanto Japan	Herbicide tolerant, Insect resistant	2004 (MON-00863-5xMON-00810-6xMON-00603-6)	2004	2004
	B.t. Cry34/35Ab1 EventDAS-59122-7	DuPont	Herbicide tolerant, Insect resistant	2006 (DAS-59122-7)	2006	2005
	MON88017 x MON810	Monsanto Japan	Herbicide tolerant, Insect resistant	2006 (MON-88017-3 x MON-00810-6)	2006	2005
	B.t. Cry34/35Ab1 EventDAS-59122-7 x 1507	DuPont	Herbicide tolerant, Insect resistant	2006 (DAS-01507-1 x DAS-59122-7)	2006	2005
	B.t. Cry34/35Ab1 EventDAS-59122-7 x NK603	DuPont	Herbicide tolerant, Insect resistant	2006 (DAS-59122-7 x MON-00603-6)	2006	2005
	B.t. Cry34/35Ab1 EventDAS-59122-7 x 1507 x NK603	DuPont	Herbicide tolerant, Insect resistant	2006 (DAS-59122-7 x DAS-01507-1 x MON-00603-6)	2006	2005
	LY038	Monsanto Japan	High lysine content			2007
Cotton	531	Monsanto Japan	Insect resistant	2004 (MON-00531-6)	1997	2001
	757	Monsanto Japan	Insect resistant	2005 (MON-00757-7)	2003	2001
	1445	Monsanto Japan	Herbicide tolerant	2004 (MON-01445-2)	1998	2001
	10211	Monsanto Japan	Herbicide tolerant		-	2001
	10215	Monsanto Japan	Herbicide tolerant		1998	2001
	10222	Monsanto Japan	Herbicide tolerant		1998	2001
	15985	Monsanto	Insect resistant	2004 (MON-	2003	2002

		Japan		15985-7)		
	1445 x 531	Monsanto Japan	Herbicide tolerant, Insect resistant	2004 (MON-01445-2xMON-00531-6)	2003	2003
	15985 x 1445	Monsanto Japan	Herbicide tolerant, Insect resistant	2005 (MON-16985-7xMON-01445-2)	2003	2003
	LLCotton25	Bayer Crop Science	Herbicide tolerant	2006 (ACS-GH001-3)	2006	2004
	MON88913	Monsanto Japan	Herbicide tolerant	2006 (MON-88913-8)	2006	2005
	MON88913 x 15985	Monsanto Japan	Herbicide tolerant, Insect resistant	2006 (MON-88913-8 × MON-15985-7)	2006	2005
	281	Dow Chemicals Japan	Herbicide tolerant, Insect resistant	-	2005	
	3006	Dow Chemicals Japan	Herbicide tolerant, Insect resistant		-	2005
	281 x 3006	Dow Chemicals Japan	Herbicide tolerant, Insect resistant	2006 (DAS-24236-5×DAS-21023-5)	2006	2005
	281 x 3006 x 1445	Dow Chemicals Japan	Herbicide tolerant, Insect resistant	2006 DAS-24236-5×DAS-21023-5×MON-01445-2)		2006
	281 x 3006 x MON88913	Dow Chemicals Japan	Herbicide tolerant, Insect resistant	2006(DAS-24236-5×DAS-21023-5×MON-88913-8))	2006	2006
	LLCotton 25 x 15985	Bayer Crop Science	Herbicide tolerant, Insect resistant	2007 (ACS-GH001-3×MON-15985-7)	2006	2006
Potato	BT6	Monsanto Japan	Insect resistant	Not needed	N/A	2001
	SPBT02-05	Monsanto Japan	Insect resistant	Not needed	N/A	2001
	RBMT21-129 (NLP)	Monsanto Japan	Insect resistant and virus resistant	Not needed	N/A	2001
	RBMT21-350 (NLP)	Monsanto Japan	Insect resistant and virus resistant	Not needed	N/A	2001
	RBMT22-82 (NLP)	Monsanto Japan	Insect resistant and virus resistant	Not needed	N/A	2001
	SEMT15-15 (NLY)	Monsanto Japan	Insect resistant and virus resistant	Not needed	N/A	2003
	RBMT15-101	Monsanto Japan	Insect resistant and virus resistant	Not needed	N/A	2003
	New Leaf Y Potato SEMT15-02	Monsanto Japan	Insect resistant and virus resistant	Not needed	N/A	2003

Soybean	40-3-2	Monsanto Japan	Herbicide tolerant	2005 (MON-04032-6)	2003	2001
	260-05	DuPont	High oleic acid	2007 (DD-026005-3)	2003	2001
	A2704-12	Bayer Crop Science	Herbicide tolerant	2006 (ACS-GM005-3)	2003	2001
	A5547-127	Bayer Crop Science	Herbicide tolerant	2006 (ACS-GM006-4)	2003	2001
Sugar beet	T120-7	Bayer Crop Science	Herbicide tolerant	Not needed	1999	2001
	77	Monsanto Japan	Herbicide tolerant	Not needed	2003	2003
	H7-1	Monsanto Japan	Herbicide tolerant	Not needed	-	2003
Total approval numbers				BSP	Feed	Food
				42 (15*)	73 (45**)	77
For each biotechnology variety, the years safety approvals were granted are shown for BSP environmental (import and planting), feed and food safety. 'None' indicates the safety has not been confirmed by the Government of Japan. Potato and sugar beet are imported to Japan only as processed foods, thus indicated as 'Not needed' for import and planting. 'N/A' means not applicable. * in BSP approvals indicates temporary approvals until full risk assessment completes. ** in Feed approvals indicates the number of events excluding stacks, which appear on the feed approval table by MAFF.						

The list of approved events for food is also available on line from MHLW (http://www.mhlw.go.jp/english/topics/food/pdf/sec01.pdf).

List of the approved biotech additives

Products	Name	Characteristics	Developer	Public announcement
α-amylase	TS-25	Improved productivity	Novozymes A/S	2001
	BSG-amylase	Improved productivity	Novozymes A/S	2001
	TMG-amylase	Improved productivity	Novozymes A/S	2001
	SP961	Improved productivity	Novozymes A/S	2002
	LE399	Improved productivity	Novozymes A/S	2005
	SPEZYME FRED	Improved heat tolerance	Genencor International, Inc.	2007
Chymosin	Maxiren	Improved productivity	DMS	2001
	CHY-MAX	Improved productivity	CHR HANSEN A/S	2003
Pullulanase	Optimax	Improved productivity	Genencor International, Inc.	2001
	SP962	Improved productivity	Novozymes A/S	2002

Lipase	SP388	Improved productivity	Novozymes A/S	2001
	NOVOZYM677	Improved productivity	Novozymes A/S	2003
Riboflavin	Riboflavin (Vitamin B2)	Improved productivity	F. Hoffmann-La Roche	2001
Glucoamylase	AMG-E	Improved productivity	Novozymes A/S	2002

List of the biotech crops under food safety assessment process

Plant species	Trait or Variety	Applicant/Developer	Characteristics
Corn	MIR604	Monsanto Japan	Insect resistant
	6275	Dow Chemical	Insect resistant and Herbicide tolerant
	MON89034	Monsanto Japan	Insect resistant
	LY038 x MON810	Monsanto Japan	High lysine content and Insect resistant
Papaya	55-1	Hawaii Papaya Industry Association	Virus resistant
Soybean	MON89788	Monsanto Japan	Herbicide tolerant

List of the biotech additives under food safety assessment process

Products	Name	Applicant/Developer	Characteristics
Lipase	HL1232	Novozymes A/S	Improved productivity
	SP990	Novozymes A/S	Improved productivity
Pectinase	SP527	Novozymes A/S	Improved productivity
Protease	Brewers Clarex, MaxiPro XF	DMS	Improved productivity

Products in Field Trials

The Japanese government requires all entities to obtain approval before performing field trials of biotech crops. The following table shows the list of those biotech crops approved for field trial in CY2006 and 2007(as of July 2007). The list and archives are also available on line from Japan Biosafety Clearing House (J-BCH) website; http://www.bch.biodic.go.jp/english/lmo.html.

LMO of which Type 1 Use Regulation is approved under the Cartagena Protocol domestic Law

Approval Date	Name of the type of Living Modified Organism	Applicant
2007/6/26	Rice containing cedar pollen peptide(*7Crp, Oryza sativa* L.) (7Crp#10)	National Institute of Agrobiological Sciences(NIAS)
2007/5/30	Maize tolerant to glyphosate herbicide and tolerant to acetolactate synthase inhibitor (*gat4621, zm-hra, Zea mays* subsp. *mays* (L). Iltis.) (DP-098140-6, OECD UI:DP-098140-6)	Du Pont Kabushiki Kaisha

2007/5/30	Soybean high oleic acid and tolerant to acetolactate synthase inhibitor (*gm-fad2-1, gm-hra, Glycine max* (L). Merr.) (DP-305423-1, OECD UI:DP-305423-1)	Du Pont Kabushiki Kaisha
2007/5/30	Cotton resistant to Lepidoptera (*Modified cry1Ab, Gossypium hirsutum* L.) (COT67B, OECD UI:SYN-IR67B-1)	Syngenta Seeds K. K.
2007/5/30	Cotton resistant to Lepidoptera (*Modified vip3A, Gossypium hirsutum* L.) (COT102, OECD UI:SYN-IR102-7)	Syngenta Seeds K. K.
2007/5/17	Maize resistant to Lepidoptera and tolerant to glufosinate herbicide (Modified *cry1Ab, bar, Zea mays* subsp. *mays* (L.) Iltis) (Event176, OECD UI: SYN-EV176-9)	Syngenta Seeds K.K.
2007/5/17	Oilseed rape tolerant to glufosinate herbicide (*pat, Brassica napus* L.) (Topas 19/2, OECD UI :ACS-BN007-1)	Bayer Crop Science K.K.
2007/4/24	Sugar beet tolerant to glyphosate herbicide(modified *cp4 epsps, Beta vulgaris* L. ssp. *vulgaris var. altissima*)(H7-1,OECD UI: KM-000H71-4)	Monsanto Japan Limited
2007/4/24	High oleic acid soybean (*GmFad2-1, Glycine max* (L.) Merr.) (260-05, OECD UI: DD-026005-3)	Du Pont Kabushiki Kaisha
2007/4/24	Maize resistant to Lepidoptera and tolerant to glufosinate herbicide (Modified *cry1Ab, pat, Zea mays* subsp. *mays* (L.) Iltis) (Bt11, OECD UI: SYN-BT011-1)	Syngenta Seeds K.K.
2007/4/24	Glufosinate herbicide tolerant and fertility restored oilseed rape(Modified *bar, barstar, Brassica napus* L.)(RF3, OECD UI :ACS-BN003-6)	Bayer Crop Science K.K.
2007/3/22	High cellulose rich white poplar trg300-1(*AaXEG2, Populus alba* L.)	Incorporated Administrative Agency Forest Tree Breeding Center, Japan
2007/3/22	High cellulose rich white poplar trg300-2(*AaXEG2, Populus alba* L.)	Incorporated Administrative Agency Forest Tree Breeding Center, Japan
2007/1/29	Maize resistant to Lepidoptera and torelant to glufosinate herbicide (*cry1Ac, bar, Zea mays subsp. mays* (L.) Iltis) (DBT418, OECD UI: DKB-89614-9)	Monsanto Japan Limited
2007/1/29	Cotton tolerant to glufosinate herbicide and resistant to Lepidoptera (Modified *bar,* Modified *cry1Ac, cry2Ab, Gossypium hirsutum* L.) (LLCotton25×15985, OECD UI:ACS-GH001-3×MON-15985-7)	Bayer Crop Science K.K.

2006/11/24	Soybean tolerant to glufosinate herbicide(*pat, Glycine max* (L.) Merr.)(A2704-12, OECD UI: ACS-GM005-3)	Bayer Crop Science K.K.
2006/11/24	Soybean tolerant to glufosinate herbicide(*pat, Glycine max* (L.) Merr.)(A5547-127, OECD UI: ACS-GM006-4)	Bayer Crop Science K.K.
2006/9/22	Oilseed rape tolerant to glufosinate herbicide and male sterile (*bar, barnase, Brassica napus* L.)(MS8,OECD UI :ACS-BN005-8)	Bayer Crop Science K.K.
2006/7/4	Soybean tolerant to glyphosate herbicide and tolerant to acetolactate synthase inhibitor(*gat, gm-hra, Glycine max* (L.) Merr.) (DP-356043-5, OEC D UI: DP356043-5)	Du Pont Kabushiki Kaisha Syngenta Japan KK
2006/7/4	Maize resistant to Lepidoptera and tolerant to glufosinate herbicide(*cry 1Ab, pat, Zea mays* subsp. *mays* (L.) Iltis.) (Bt10)	Syngenta Japan KK
2006/6/12	Cotton resistant to Lepidoptera, and tolerant to glufosinate herbicide and glyphosate herbicide (*cry1F, cry1Ac, pat, cp4 epsps, Gossypium hirsutum* L.) (281×3006×MON88913, OECD UI : DAS-24236-5×DAS-21023-5×MON-88913-8)	Dow Chemical Japan Ltd.
2006/6/12	Cotton resistant to Lepidoptera, and tolerant to glufosinate herbicide and glyphosate herbicide (*cry1F, cry1Ac, pat, cp4 epsps, Gossypium hirsutum* L.)(281×3006×1445, OECD UI : DAS-24236-5×DAS-21023-5×MON-01445-2)	Dow Chemical Japan Ltd.
2006/5/29	Maize resistant to Lepidoptera and tolerant to glufosinate herbicide (*cry 1F, bar, Zea mays* subsp. *mays* (L). Iltis.)(TC6275, OECD UI: DAS-06275-8)	Dow Chemical Japan Ltd.
2006/5/29	Oilseed rape tolerant to glyphosate herbicide(*cp4 epsps, gox, Brassica napus* L.)(RT200, OECD UI : MON-89249-2)	Monsanto Japan Limited
2006/5/2	Lepidoptera resistant maize(*cry 1A.105, cry2Ab2, Zea mays* subsp. *mays* (L). Iltis.)(MON89034)	Monsanto Japan Limited
2006/5/2	Soybean tolerant to glyphosate herbicide(*cp4 epsps, Glycine max* (L.) Merr.)(MON89788-1)	Monsanto Japan Limited
2006/5/2	A Rose Variety With Modified Flavonoid Biosynthetic Pathway WKS82/130-9-1 (*F3' 5' H, 5AT, Rosa hybrida*)(OECD UI:IFD-52901-9)	SUNTORY LIMITED
2006/5/2	A Rose Variety With Modified Flavonoid Biosynthetic Pathway WKS82/130-4-1 (*F3' 5' H, 5AT, Rosa hybrida*)(OECD UI:IFD-52401-4)	SUNTORY LIMITED

2006/4/10	Maize resistant to Coleoptera and Lepidoptera, and tolerant to glufosinate herbicide and glyphosate herbicide (*cry34Ab1, cry35Ab1, cry1F, pat, cp4 epsps, Zea mays* subsp. *mays* (L.) Iltis) (59122×1507×NK603, OECD UI: DAS-59122-7×DAS-01507-1×MON-00603-6)	Du Pont Kabushiki Kaisha
2006/4/10	Maize resistant to Coleoptera and tolerant to glufosinate herbicide and glyphosate herbicide (*cry34Ab1, cry35Ab1, pat, cp4 epsps, Zea mays* subsp. *mays* (L.) Iltis) (59122×NK603, OECD UI: DAS-59122-7×MON-00603-6)	Du Pont Kabushiki Kaisha
2006/4/10	Maize resistant to Lepidoptera and Coleoptera and tolerant to glufosinate herbicide (*cry1F, cry34Ab1, cry35Ab1, pat, Zea mays* subsp. *mays* (L.) Iltis) (1507×59122, OECD UI: DAS-01507-1× DAS-59122-7)	Du Pont Kabushiki Kaisha
2006/4/10	Cotton resistant to Lepidoptera and tolerant to glufosinate herbicide(*cry1F, cry1Ac, pat, Gossypium hirsutum* L.) (281×3006, OECD UI : DAS-24236-5×DAS-21023-5)	Dow Chemical Japan Ltd.
2006/4/10	Maize tolerant to glyphosate herbicide and resistant to Coleoptera and Lepidoptera (*cp4 epsps, cry3Bb1, cry1Ab, Zea mays* subsp. *mays* (L.) Iltis) (MON88017×MON810, OECD UI: MON-88017-3×MON-00810-6)	Monsanto Japan Limited
2006/4/10	Maize tolerant to glufosinate herbicide (*bar, Zea mays* subsp. *mays* (L.) Iltis) (DLL25, OECD UI: DKB-89790-5)	Monsanto Japan Limited
2006/4/10	Maize tolerant to glyphosate herbicide and resistant to Coleoptera (*cp4 epsps, cry3Bb1, Zea mays* subsp. *mays* (L.) Iltis) (MON88017, OECD UI: MON-88017-3)	Monsanto Japan Limited
2006/4/10	Maize resistant to Coleoptera and tolerant to glufosinate herbicide(*cry34Ab1, cry35Ab1, pat, Zea mays* subsp. *mays* (L.) Iltis) (*B.t.* Cry34/35Ab1 Event DAS-59122-7, OECD UI: DAS-59122-7)	Du Pont Kabushiki Kaisha
2006/3/10	Oilseed rape tolerant to glyphosate herbicide(*cp4 epsps, gox, Brassica napus* L.)(RT73, OECD UI : MON-00073-7)	Monsanto Japan Ltd.
2006/2/10	Cotton tolerant to glyphosate herbicide and resistant to Lepidoptera (*cp4 epsps, cry1Ac, cry2Ab, Gossypium hirsutum* L.)(MON 88913×15985, OECD UI : MON-88913-8× MON-15985-7)	Monsanto Japan Ltd.
2006/2/10	Maize tolerant to glufosinate herbicide (*pat, Zea mays subsp.mays* (L.) Iltis) (T14, OECD UI :ACS-ZM002-1)	Bayer Crop Science K.K.
2006/2/10	Cotton tolerant to glyphosate herbicide(*cp4 epsps, Gossypium hirsutum* L.)(MON 88913, OECD UI : MON-88913-8)	Monsanto Japan Ltd.

2006/2/10	Alfalfa tolerant to glyphosate herbicide (*cp4 epsps, Medicago sativa* L.) (J101×J163, OECD UI:MON-00101-8×MON-00163-7)	Monsanto Japan Ltd.
2006/2/10	Alfalfa tolerant to glyphosate herbicide (*cp4 epsps, Medicago sativa* L.) (J163, OECD UI: MON-00163-7)	Monsanto Japan Ltd.
2006/2/10	Alfalfa tolerant to glyphosate herbicide (*cp4 epsps, Medicago sativa* L.) (J101, OECD UI: MON-00101-8)	Monsanto Japan Ltd.
2006/2/10	Cotton tolerant to glufosinate herbicide (*bar, Gossypium hirsutum* L) (LLCotton25, OECD UI:ACS-GH001-3)	Bayer Crop Science K.K.

Stacked Events

Japan requires separate environment approvals for stacked events - those that combine two already approved traits, such as herbicide tolerance and insect resistance.

For environment safety approvals of stacked events, it is not always necessary to perform field trials. While MAFF and MOE require environment safety review by their experts, the data and information on the parents may be used and it is generally unnecessary to carry out field trials on the stacked events.

For food safety approvals, the FSC presented an opinion paper on January 29, 2004 on its reviews of crossed events between biotech and non-biotech events and stacked events. In this paper, the FSC categorized biotech events into three groups: 1) introduced genes which do not influence host metabolism and mainly endow the hosts with insect resistance, herbicide tolerance or virus resistance, 2) introduced genes which alter host metabolism and endow the hosts with high nutritional component concentration or suppression of cell wall degradation by promoting or inhibiting specific metabolic pathways, and 3) introduced genes which utilize certain metabolites to synthesize new metabolites the hosts originally do not produce.

The FSC requires a safety approval on the crossed event if the crossing occurs above the subspecies level between a biotech event and a non-biotech event, and if the crossing occurs biotech events in category 1. The FSC also requires safety approvals on stacked events between those in category 1 if the amount consumed by humans, the edible part or processing method is different from that of the parents. The FSC requires safety approvals on stacked events between biotech events in 1 and 2, 1 and 3, 2 and 2, 3 and 3, and 2 and 3. Most stacked events that result from traditional crossbreeding do not require a safety review.

For feed safety of stacked events, MAFF requires approvals from the Expert Panel on Recombinant DNA Organisms of the Agricultural Material Committee (AMC). Unlike the feed safety full approvals, the approvals by the Expert Panel are neither subject to MAFF Minister notification nor public comments.

Coexistence

A guideline issued by MAFF on February 24, 2004, requires that before field trials are performed, detail information including preventive measures for crossing with the same plant species in surrounding environment, such as buffer zones, must be made public on websites and through explanatory meetings for local residents.

The buffer zones should isolate field trials from the same plant species using the minimum distances stated below.

Name of the field tested plant	Minimum isolation distance

Rice	26 meters (temporarily amended in April 2005 from 26 meters, and proposed new distance of 30 meters under the comment period until January 24, 2006)
Soybean	10 meters
Corn (applicable only on those with food and feed safety approvals)	600 meters, or 300 meters with the presence of a windbreak
Rapeseed (applicable only on those with food and feed safety approvals)	600 meters, or 400 meters if non-recombinant rapeseed is planted to flower at the same time of the field tested rapeseed. A width of 1.5 meters surrounding field tested plants as a trap for pollens and pollinating insects

If the field tested rice or soybeans have not received either food or feed approval, then, the same plant species should be planted as an index (index plant) to flower at the same time of the field tested plant to confirm if crossing took place between the inside and outside of the test field, and at least 10,000 seeds should be harvested (in the cases xenia is generated, seeds showing xenia are selected), and tested through analytical methods such as PCR that can specifically detect introduced genes of the field tested plant, or the presence of drug resistance if the introduction includes drug resistance, to confirm if crossing took place.

Following is a table of the range of "same plant species."

Field tested plant	Plant belong to the same plant species
Rice (*Oryza sativa* L.)	Rice (*Olyza sative* L.)
Soybean (*Glycine max* L.)	Soybean (*Glycine max* L.)
Corn (*Zea mays* L.)	Corn (*Zea mays* L.) Teosinte (*Zea mays* subsp. *Mexicana*)
Rapeseed (*Brassica napus*)	Rapeseed (*Brassica napus*) Chinese cabbage, Radish, *Komatsuna*, Quing-geng-cai, *Tsukena*, etc. (*Brassica rapa*) *Karashina*, *Takana*, etc. (*Brassica juncea*) *Kairan* (*Brassica alboglabra*)
Tomato (*Lycopsicum esculentum* Mill.)	Tomato (*Lycopsicum esculentum* Mill.)
Cotton (*Gossypium hirsutum* L.)	Cotton (*Gossypium hirsutum* L.)
Alfalfa (*Medicago sativa*)	Alfalfa (*Medicago sativa*)
Potato (*Solanum tuberosum*)	Potato (*Solanum tuberosum*)
Sugar beet (*Beta vulgaris*)*	Sugar beet, Beet, etc. (*Beta vulgaris*)
Papaya (*Carica papaya L.*)*	Papaya (*Carica papaya L.*)

*: Proposed to be added to the list under the comment period Fall 2006

U.S.-Japan Regulatory Reform Initiative

Established in 2001, the U.S.-Japan Regulatory Reform and Competition Policy Initiative (Regulatory Reform Initiative) aims to enhance economic growth by creating new business opportunities, strengthening competition, and improving the overall business environment. As a key component of the U.S.-Japan Economic Partnership for Growth, both Governments exchange annual recommendations under the Initiative and, following working and high-level discussions, prepare this annual Report to the Leaders to outline progress. A range of issues were covered in 2006-7, including the management of Japan's feed biotechnology approval process and biotech IP and testing requirements for U.S. potatoes. (For more information, please see pgs. 39-40 of the Sixth Report to the Leader on the U.S.-Japan Regulator Reform and Competion Policy Initiative June 6, 2007)

Local Government Regulations

There are a number of local rules relating to agricultural biotechnology in Japan. These are listed below by prefecture along with the prefecture's relative agricultural production. Most, if not all, of these rules are political responses to popular concerns and are not based in science.

1. Hokkaido (Ordinance)

In 2006, Japan's northernmost island of Hokkaido is the country's bread basket and, in many instances, leads on agricultural policy issues. Hokkaido became the first prefecture in the country to implement strict local regulations governing the open-air cultivation of biotech crops. The Hokkaido rules set minimum distances between biotech crop fields and others. The distance is at least 300 meters for rice, 1.2 kilometers for corn and 2 km for sugar beets. The distances are about twice as large as those set at the national level MAFF for its research entities.

Under the current regulations, individual farmers wishing to plant open-air biotech crops must complete a series of complicated steps to request approval from the Hokkaido Governor's Office. For farmers, failure to follow these procedures could result in up to one year imprisonment and a fine of as much as 500,000 yen ($4,167). First, farmers must host public meetings at their own expense with neighboring farmers, agricultural cooperative members, regional officials and other stakeholders. At these meetings, they must announce their intention to plant biotech crops and explain how they will ensure that their crops do not mix with non-biotech crops. Afterwards, the farmers must also draft complete minutes of these meetings to submit to the Governor's Office.

Next, farmers must complete a detailed application for submission to the governor's office that explains their plans for growing biotech crops. The application requires precise information on methods that will be used to monitor the crops overall as well as measures for preventing cross-pollination, means for testing for biotech contamination, and procedures for responding to emergencies.

Finally, farmers must pay a processing fee of 314,760 yen ($2,623) to the Hokkaido Governor's Office to cover the costs of reviewing their applications. If approval is initially granted but major changes to the application are made later, then farmers must also pay an additional reprocessing fee of 210,980 yen ($1,758).

Institutions that want to conduct research using open-air biotech farming are also subject to a regulatory process similar to that imposed upon farmers. After receiving government designation as legitimate research institutions, these organizations must then give formal notification of their biotech research activities and submit extensive paperwork to the Hokkaido governor's office for approval. They must also provide detailed test cultivation plans for local government panel review.

However, research institutions are not required to hold explanatory meetings with neighbors or pay application processing fees to the Hokkaido government. Furthermore, while subject to fines as large as 500,000 yen ($4,167) for non-compliance, employees of research institutions are not subject to imprisonment if they ignore biotech regulations. This lenience granted to research institutions is an attempt to make the regulations more reflective of Hokkaido resident preferences.

For both individual farmers and research institutions, the Hokkaido Governor's Office decides whether to approve the applications based on the recommendations of the Hokkaido Food Safety and Security Committee (HFSSC). The HFSCC serves as an advisory board to the governor and consists of fifteen members representing academia, consumers and food producers with the knowledge of food safety. Within HFSCC, there is also a separate subcommittee made up of six professional researchers who study the application from scientific point of view. The HFSSC as a whole is authorized by the governor to order applicants to change their cultivation plans if they feel it is necessary.

Since the 2006 implementation of Hokkaido's biotech regulatory regime, however, no farmers or research institutions have submitted any requests to the Hokkaido governor's office to grow open-air biotech crops. Difficulties in complying with the new Hokkaido biotech regulations, along with continued consumer

anxiety about the safety of biotech products and a shift towards conducting biotech crop research inside enclosed environments, all effectively halted attempts at open-air cultivation of biotech crops. Therefore, the HFSSC has not yet had the opportunity to review let alone approve or reject applications. It remains to be seen how strict the committee would be in evaluating individual applications.

Recently, the Hokkaido prefectural government hosted a series of public forums to seek input on whether the biotech regulations should be revised. Attendees did not reach a consensus, but it was clear at the meetings that local anxiety about biotech crops remains high.

Household surveys taken in 2004 and 2005 by the Hokkaido government before the implementation of the biotech regulations showed that while 80% of respondents are concerned about consuming biotech crops, nearly 70% of respondents also support further research testing on biotech crops.

2. Iwate (Guidelines)

The biotech crop guidelines were established in September 2004. The guidelines state that the prefectural government in cooperation with local governments and local agricultural cooperatives request farmers who plan growing biotech crops to stop it. For research institutes, the prefectural government requests that they strictly follow the experimental guidelines when they grow biotech crops.

3. Niigata (Ordinance)

Niigata put a stringent ordinance into effect in May 2006. It obliges farmers to get permission to grow biotech crops, while research institutes must file reports on open-air experiments. Violators face up to a year in prison or fines of up to 500,000 yen (approximately $4,300).

4. Ibaragi (Guidelines)

The biotech crop guidelines were set up in March 2004. The guidelines state that a person who plans to grow biotech crops in open-air fields must provide information to the prefectural government before planting the crops. The person must make sure that s/he gets acknowledgement from local governments, nearby farmers and farm cooperatives of the region. The person must take measures to prevent hybridization with conventional crops and commingling with ordinary foods.

5. Chiba (Guidelines)

Based on the ordinance on food safety and assurance that came into force in April 2006, the government is in the process of drawing up the guidelines on growing biotech crops.

6. Shiga (Guidelines)

Shiga Prefectural government is eager to promote biotechnology. However, consumers still have concern about biotech crops. The prospect of consumer backlash makes farmers nervous about biotech crops. Thus until consumers are more accepting about biotech crops, the government decided to adopt guidelines on growing biotech crops. The guidelines were established in 2004.

The guidelines state that the government requests farmers to exercise restraint in growing biotech crops commercially. For test plats, the government requests farmers to take measures to prevent hybridization and commingling. The guidelines are not applied to research institutions.

7. Kyoto (Guidelines)

Based on the ordinance of promoting food safety and assurance that came into force in 2004, the government has drawn up draft guidelines on growing biotech crops. The guideline states that a person who is going to grow biotech crops is obliged to take measures to prevent hybridization and commingling. Biotech crops addressed by the guidelines are rice, soybeans, corn and rapeseed.

The government has asked for comments of the draft guidelines. The due date is August 25, 2006.

8. Hyogo (Guidelines)

The biotech crop guidelines in Hyogo were enacted on March 31, 2006. In the introduction, it is stated that though biotech crops of which safety was confirmed based on the law are allowed to be grown and used for human consumption, consumers are concerned about the implications of biotech crops for human health, the environment and farmers are concerned about hybridization and commingling of biotech crops with conventional crops. Thus, the government decided to establish the guidelines.

The basic policy of the guidelines is twofold. One is to give guidance to farmers to carefully manage production to avoid causing any confusion on the aspects of production, distribution and marketing. The other is to give guidance to label the biotech products for consumers' right to choose.

9. Tokushima (Guidelines)

Tokushima Prefecture implemented an ordinance to promote food safety and assurance in December 2005. Based on the ordinance, the guidelines on biotech crops were established. The guidelines state that a person who grows biotech crops in open-air fields must notify the governor. The fields must be posted with a sign to tell that biotech crops are being grown.

In case of Tokushima, it is stressed that it is part of its "farm brand strategy" to compete with other production centers.

10. Imabari City in Ehime Prefecture (Guidelines)

It is not Ehime Prefecture but one of its municipalities drew up draft guidelines on biotech crops. The guidelines are to be submitted to an Imabari City assembly in September of this year.

11. Tokyo (Guidelines)

The biotech crop guidelines were enacted in May 2006. According to the guidelines, a person who plans to grow biotech crops must provide information to the Tokyo Metropolitan government.

Figure 1: Prefectures With Ordinances Or Guidelines On Growing Biotech Crops

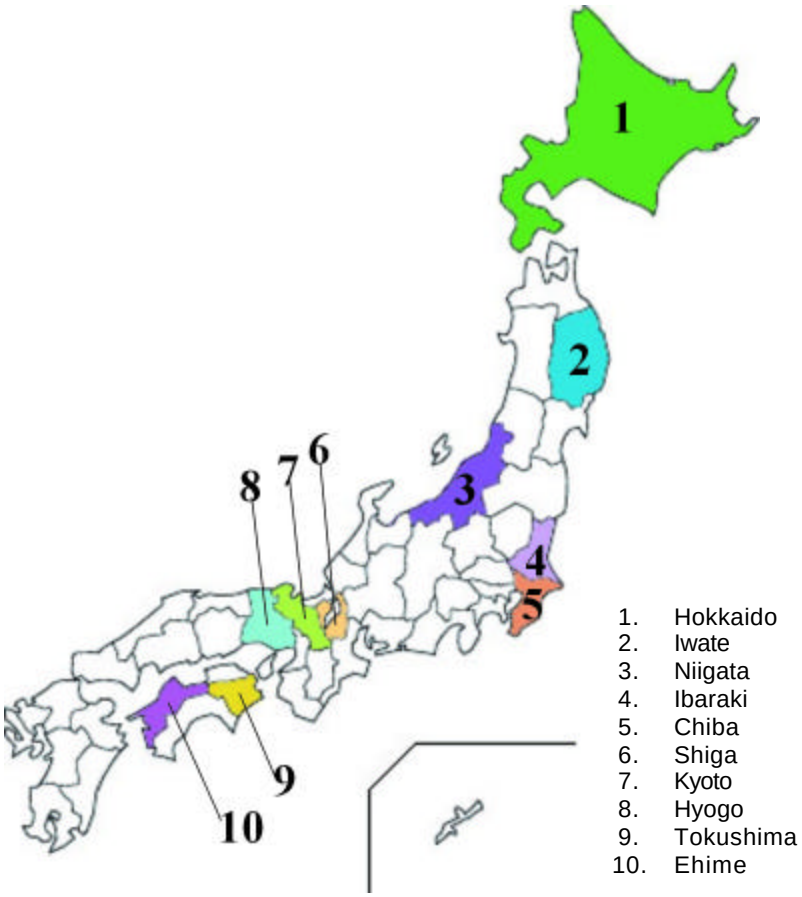


Table 1: Agricultural Output by Prefecture in 2005

Rank	Prefecture	Agricultural Output*	% of Total Agricultural Output
1	Hokkaido	9.93	12
2	Chiba	3.83	5
3	Ibaragi	3.81	5
9	Niigata	2.65	3
11	Iwate	2.38	3
22	Hyogo	1.23	2
25	Ehime	1.18	1
31	Tokushima	0.95	1
39	Kyoto	0.65	1
42	Shiga	0.59	1

Source: Ministry of Agriculture, Forestry and Fisheries

* Unit: Billion US Dollars

Labeling

MAFF and MHLW have implemented labeling requirements under the Food Sanitation Law and the Japan Agricultural Standards (JAS) Law, respectively for biotech products that have been approved in Japan. MAFF introduced the biotech labeling in response to a demand of "the consumers' right to know" while MHLW introduced its labeling from a more scientific standpoint to clarify that the biotech ingredients used are those whose safety is confirmed. Although the labeling requirements for the Ministries are listed separately, both sets of requirements are basically identical. MAFF's labeling policy on biotech traits may be found at the MAFF website (http://www.maff.go.jp/soshiki/syokuhin/hinshitu/organic/eng_yuki_gmo.pdf).

Both MAFF and MHLW biotech labeling schemes for non-biotech products are based on and rely on IP handling of non-biotech ingredients from production to final processing. The initial suppliers and operators of distribution of the products are responsible for supplying this certification to the exporter to Japan, who in turn supply its certification of IP handling in the U.S. to Japan's food importers or manufacturers. The English version of the manuals for the IP handling of corn and soybeans, and potatoes are available at MAFF website (http://www.maff.go.jp/soshiki/syokuhin/hinshitu/e_label/file/Labeling/DistributionManu_SoyCorn.pdf) and (http://www.maff.go.jp/soshiki/syokuhin/hinshitu/e_label/file/Labeling/DistributionManu_potato.pdf), respectively.

As shown below, the 31 foods currently subject to JAS labeling requirements (and MHLW labeling requirements) were selected because they are made from ingredients that could include biotech products and because traces of introduced DNA or protein can be identified in the foods. If the weight content of the ingredient to be labeled in these 31 foods exceeds 5 percent of total weight of the foods, they must be labeled with either the phrase "Biotech Ingredients Used" or "Biotech Ingredient Not Segregated" if the raw ingredient does not accompany certificates of the IP handling. In order to be labeled "Non-Biotech," the processor must be able to show that the ingredient to be labeled was IP handled from production through processing according to the above manuals.

Items subject to labeling	Ingredient to be labeled
1. Tofu (soybean curd) and fried tofu	Soybean
2. Dried soybean curd, soybean refuse, yuba	Soybean
3. Natto (fermented soybean)	Soybean
4. To-nyu (soy milk)	Soybean
5. Miso (soybean paste)	Soybean
6. Cooked soybean	Soybean
7. Canned soybean, bottled soybean	Soybean
8. Kinako (roasted soybean flour)	Soybean
9. Roasted soybean	Soybean
10. Item containing food of items 1 to 9 as a main ingredient	Soybean
11. Item containing soybean (for cooking) as a main ingredient	Soybean
12. Item containing soybean flour as a main ingredient	
13. Item containing soybean protein as a main ingredient	Soybean
14. Item containing edamame (green soybean) as a main ingredient	Soybean
15. Item containing soybean sprouts as a main ingredient	
16. Corn snacks	Edamame
17. Corn starch	
18. Popcorn	Soybean sprouts
19. Frozen corn	
20. Canned or bottled corn	Corn

21. Item containing corn flour as a main ingredient	Corn
22. Item containing corn grits as a main ingredient	Corn
23. Item containing corn (for processing) as a main ingredient	Corn
24. Item containing food of items 16 to 20 as a main ingredient	Corn Corn
25. Frozen potato	Corn
26. Dried potato	Corn
27. Potato starch	
28. Potato snacks	Corn
29. Item containing food of items 25 to 28 as a main ingredient	Potato
30. Item containing potato (for processing) as a main ingredient	Potato Potato
31. Item containing alfalfa as a main ingredient	Potato Potato Potato
	Alfalfa

In addition to the 31 food items in the table, Japan applies the biotech labeling on the biotech high oleic acid soybean products even though the oil extracted from the soybean does not contain traces of the introduced genes or proteins.

Monitoring of "Biotech" or "Non-Biotech" Labels

Japan recognizes that even though proper IP handling and distribution methods are used, the possibility exists for adventitious commingling of biotech products in non-biotech products. Therefore, for corn and soybeans, Japan set an informal tolerance of 5% for biotech ingredients in products that are labeled "non-biotech." This tolerance only applies to events that have been approved in Japan. If MAFF or MHLW finds a product labeled "non-biotech" that has a biotech (corn and soybeans) content of over 5 %, it is determined that the IP handling had not been carried out adequately. The ministry orders the manufacturer or importer to present the IP handling certificates to verify them and issues guidance directing it to correct the product's label to show that it was made with "Biotech Ingredients."

Monitoring for Unapproved Biotech Events

Japan has a zero tolerance for unapproved biotech events in foods. To assure compliance, a sampling program is in place to test both import shipments and processed food products at the retail level. Any detection of an unapproved biotech event in a food is deemed a violation of Japan's Food Sanitation Law. As a part of the monitoring program for imported foods, testing at ports is handled by MHLW directly, while local health authorities handle testing for processed foods at the retail level. All testing is performed according to sampling and testing criteria set by MHLW. If the detection is at the port, the shipment must be re-exported or destroyed. If the detection is at the retail level, the manufacturer of the product must issue an immediate recall. The main products currently being tested are rice, corn, soybeans, and papayas.

Under the Feed Safety Law, MAFF monitors quality and safety of imported feed ingredients at the ports. All biotech derived plant materials to be used as feed in Japan must obtain approvals for feed safety from MAFF. However, as an exemption from the regulation, MAFF has set a 1% tolerance for the unintentional commingling of biotech products in feed that are approved in other countries but not yet approved in Japan. To apply the exemption, the exporting country must be recognized by the MAFF minister as having a safety assessment program that is equivalent to or stricter than that of Japan.

BioSafety Protocol Implementation (dealing with LMOs)

After it ratified the Biosafety Protocol in November 2003, Japan implemented the "*Law Concerning the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Living Modified Organisms*" on February 19, 2004. Although the details on how to implement the requirements of the first sentence of paragraph 2(a) of Article 18 of the Protocol on export of LMOs have not been determined yet, Japan presented its view on compliance to the requirements in November 2004 at a workshop in Bonn.

For export of LMOs directly used for food, feed and processing (FFP), Japan proposed that the Parties shall attach the following information along with the form prescribed by the Regulations related to the Enforcement of the Law or its package/container or consignment invoice when LMOs for FFP is exported; "*the LMOs 1) "may contain" living modified organisms, 2) are not intended for intentional introduction into the environment, and 3) accompany information on contact point (name, address, contact details of the exporter and importer)*".

At the workshop, Japan, as an importing Party, stated that it does not have any threshold levels for unapproved LMOs, and it does not feel it is necessary to set an international standard for threshold levels of approved LMOs. Further, individual parties based on their own labeling requirements and consumer interests, etc. must determine these threshold levels.

Japan stated it is necessary to use the "may contain" language if there is a possibility of unintentional commingling of LMOs in a non-LMO FFP cargo, but it is not necessary to have specific documentation supporting this claim when the degree of the commingling meets the acceptable levels determined independently by the importing Parties. Japan recommended to adopt OECD's the unique identifier system because it assures access to necessary information through Biosafety Clearing House (BCH).

Biotech Crop Development

Japan is one of the leading countries in the world in the field of biotech research. A number of public research institutes are active in plant and industrial biotech research and development. One of the most popular crops for transformation is rice. For instance, Japan has invested over $400 million dollars on a rice genomic project which completed a full sequencing of the rice genome. Consequently, there are a number of experimental field trials including rice containing cedar pollen peptide to suppress allergies and rice tolerant to low iron availability. However agricultural biotechnology for commercial application is lagging far behind and there are no new food products in the pipeline for commercialization. Following is the list of on-going research from presentations in local academic conferences and seminars.

- Development of male sterile Brassica crops using endogenous promoters and genes
- Transgenic protein production by silk grand.
- Production of transgenic wheat transformed with low-molecular-weight glutenin genes to better understand dough strength.
- Production of transgenic cabbage with a Bt-gene.

Much of this research is in the early experimental stage and has not progressed to field trials. Taking into consideration the time required to obtain necessary regulatory approvals, it will be years before these products are commercially available. One of the earliest candidates might be biotech rice which mitigate cedar pollen allergy developed by National Institute of Agrobiological Science in Tsukuba, Ibaraki, which could be approved as a pharmaceutical. Private industry is generally limiting itself to basic research. A uniquely colored (blue) carnation was developed by Suntory Co. but it is grown abroad and imported into Japan.

MAFF Priorities for Biotech Research and Development

On May 18, 2007, MAFF established an 11 member panel to discuss Japan's research and development of biotech crops. From May-July, the panel held a series of six meetings culminating in the release of an interim report on July 9. A final report is expected by the end of the year.

The interim report outlines seven priority research areas falling into five and ten-year timeframes.

Practical research with expected results in five years:

1) Functional foods which have health improvement effects, e.g., rice with high GABA accumulation
2) Crops resistant to complex pests, e.g., rice resistant to both filamentous fungi and bacteria
3) Crops resistant to unfavorable climates and environmental change, e.g., rice resistant to dry climate, salt damage

Research with a 10 year timeframe:

4) High valued feed crops with high-yielding ability and functionality, e.g., high-yield sorghum
5) Plants which absorb harmful substances, e.g., rice which absorb cadmium
6) Crops for biofuel, e.g., high-yield sugar cane
7) Other basic research

The priory areas were reportedly developed two core considerations in mind. First, to address technical challenges that Japanese farmers currently face; and, second, to a gain a favorable response from consumers.

Marketing

Although the food industry and the government are generally open minded about agricultural biotechnology, they are very cautious about publicly. Consumer concerns, particularly among some small but vocal consumer associations, have been strong since biotech products were first put on the market in late 1990's. As a result, the food industry is very hesitant to even attempt to provide a biotech products directly to consumers. In fact, out of a fear of a consumer backlash, retailers, particularly large supermarket chains, demanded the food industry to supply non-biotech foods - even for products that do not have to be labeled, which in turn resulted in procurement of non-biotech raw ingredients by importers. This tendency to demand non-biotech ingredients is particularly strong for foods made from soybeans such as soy sauce, tofu, miso and natto, and snack foods using corn but it also extends to corn starch and beverages using these ingredients (such as beer). Many retailers use consumer concerns to their advantage by marketing store brand products as "safer" and "more natural" than those provided by their competitors.

The retailer's hesitancy to provide a biotech product reinforces the consumer's perception that there is something wrong in biotech foods, which in turn further strengthens the perceived marketing advantage in providing non-biotech products. Once a biotech product with clear consumer benefits is put on the market, this vicious cycle may be broken.

At the same time, high premiums for non-biotech corn and oils have recently let to increased private sector interest in using biotech ingredients. Beer manufacturers are, for example, looking into the use of non-segregated corn as an ingredient. Also, in July 2007, Chiba CO-OP (a large cooperative retailer) announced that they will sell oil from 'non-segregated' rapeseed because 'the events approved by Japanese regulatory system should be considered safe.' This is a departure from past practice and generally co-ops have been critical of biotechnology.

Capacity Building and Outreach

The USDA Office of Agricultural Affairs at the U.S. Embassy in Tokyo frequently organizes activities to increase public awareness about agricultural biotechnology in Japan. Some recent examples include:

On June 20, 2007, USDA and the U.S. Consulate in Sapporo supported the Hokkaido visit of U.S. Grains Council Chairman, Vic Miller. He spoke about the safety of biotech traits used in U.S. corn production and reassured Japanese corn users that the Untied States, is and will continue to be, a reliable supplier. The day included an interview with the Hokkaido Shimbun (Hokkaido's largest newspaper) and Mr. Miller fielded questions on the safety of biotechnology and on the U.S. ability to continue to supply feed to

Hokkaido dairy farms. There was a high level of interest in the growing expansion and demand for corn for fuel ethanol in the United States. Mr. Miller then met with a local pro-biotech farmer who is a member of the Japan's Biotech Crop Discussion Group. During a press event at a local dairy farm that uses U.S. corn the questions centered on U.S. corn supply and prices, biotech corn production and the safety of biotech corn. This activity has generated three positive articles.

In April 2007, the USDA Office of Agricultural Affairs at the U.S. Embassy in Tokyo translated and distributed an essay on regulatory history of agricultural biotechnology by Dr. Fred Genthner, a Microbiologist with the U.S. Environmental Protection Agency.

In February 2007, U.S. Ambassador Schieffer met with Clive James, the Chairman of the International Service for the Acquisition of Agri-biotech Applications (ISAAA), an organization that is widely recognized as the primary source of information on the global use of biotech crops. Dr. James was in Japan promoting ISAAA's latest report titled, Global Status of Commercialized Biotech/GM Crops: 2006. The purpose of the meeting was to receive the 2006 ISAAA report and to use the Embassy's web page to publicize it. Previous Embassy-supported research shows that nearly half of the Japanese consumers do not think it is accurate that Americans (or other countries) regularly eat biotech foods. About half say knowing that Americans eat biotech foods makes them more favorable to the technology.

Reference Materials

Following is a list of website of information on agricultural biotechnology and biotech foods in English. Please note that this information is not necessarily current and you may need to download the Japanese Language Package to read the pdf files even if they are written in English.

Food Safety Commission (biotech food risk assessment standards)
http://www.fsc.go.jp/senmon/idensi/gm_kijun_english.pdf

Ministry of Agriculture, Forestry and Fisheries (Information related to agricultural biotechnology)
http://www.s.affrc.go.jp/docs/sentan/

Ministry of Health, Labor and Welfare (Information related to biotech food regulations)
http://www.mhlw.go.jp/english/topics/food/index.html

(Information on biotech food labeling)
http://www.mhlw.go.jp/english/topics/qa/gm-food/index.html

Biosafety Clearing House (Japan)
http://www.bch.biodic.go.jp/english/e_index.html